Branched devices for thoracoabdominal aneurysm repair: Early experience

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Objective: **This study reports the initial clinical results and experience with the planning of branched stent grafts in high-risk patients with thoracoabdominal aortic aneurysms (TAAAs).**
Methods: **High-risk patients with TAAAs were considered for this study. Based on evaluation with computed tomography angiography (CTA), 21 custom-made branched stent grafts were designed for the selected patients. Two patients had associated bilateral aneurysms of the common iliac arteries, so an iliac branched device was also used.**
Results: **Between August 2006 and April 2008, 23 patients (10 women, 13 men) were selected to undergo endovascular TAAA repair. Mean age was 72 years old. Two patients were excluded after 1-mm-slice CTA analysis. Eleven patients have underdone TAAA repair so far. The mean follow-up period at present is 8 months (range, 18 days-21 months). Overall technical success was accomplished in all 11 patients. Two renal artery branches occluded. Operative times varied from 3 to 8 hours. Mean contrast volume was 193 mL (range, 48-420 mL). Eight patients required a stay of ≤4 days at the intensive care unit. Three patients died. Two deaths were procedurally related: one patient died of myocardial infarction, and the other had ischemic cerebellar stroke and died 3 months later of pulmonary sepsis. The third patient was readmitted 3 days after hospital discharge and died of alcoholic pancreatitis. One man had permanent paraplegia. Two women had transitory paraparesis. Striking hematologic and systemic inflammatory abnormalities were observed.**
Conclusion: **Increasing reports on stent graft technology indicate that this procedure might become a reality in the future for endovascular treatment of complex aneurysms in all aortic segments. Branched stent grafts seem to be feasible and can be offered as an effective alternative to most patients with TAAAs, especially for those who are currently excluded from open surgical procedures. (J Vasc Surg 2008;48:30S-36S.)**

Thoracoabdominal aortic aneurysm (TAAA) repair is likely one of the most invasive and least frequently performed procedures by vascular and cardiovascular surgeons. Although highly specialized medical centers have reported 30-day, 2-year, and 5-year survival rates[1] as good as 91%, 70%, and 59%, respectively, with an operative mortality of 8.2%[2], these are not the results seen in most institutions worldwide. Overall estimates from recently published results[3] suggest a 30-day mortality of 19% and a 1-year mortality as high as 31%.[4]

It should be noted, however, that, although open surgical treatment of TAAAs may seem too aggressive because it is associated with high morbidity and mortality rates, the natural course of this disease is even worse. Of 94 patients with TAAA who did not undergo operative repair, only 24% were alive after 2 years, and half of the deaths were aneurysm related.[1]

These data are among the reasons why modern endovascular techniques are used with increasing frequency to develop a less invasive and entirely endovascular approach for the treatment of TAAAs. The first branched modular endograft system was envisioned in 2001.[5] In this report we describe our initial results and the insights we gained after experience with this exciting, evolving new technology.

METHODS

Patients with TAAAs and associated severe comorbidities, with anticipated high risk for a regular open procedure, were considered for endovascular repair. All patients had TAAAs with diameters of ≥6 cm and none had associated aortic dissection. Once the arterial anatomy was considered suitable based on the analysis with computed tomography angiography (CTA) with 1-mm slice thickness, patients were asked to give informed consent to undergo the procedure, which had previously been approved by the hospital ethics committee.

We evaluated the chest, abdomen, and pelvic CTA using adjunct three-dimensional analysis with the OsiriX freeware (OsiriX Foundation, Geneva, Switzerland), and a custom-made graft was designed and submitted to the planning team from Cook-Australia Inc (Brisbane, Australia) for fine adjustments according to their own CTA analysis and device production.

At the time of this report, we have planned 21 endografts and have already implanted 11. Our further considerations regarding graft design will be based on the experience with these 21 planned grafts, and surgical outcome will be reported for 11 patients.

Device planning and design. The implanted devices are constructed using the AAA Zenith (Cook Medical Inc, Bloomington, Ind) endograft platform comprising stainless steel Z stents and woven polyester fabric of the same

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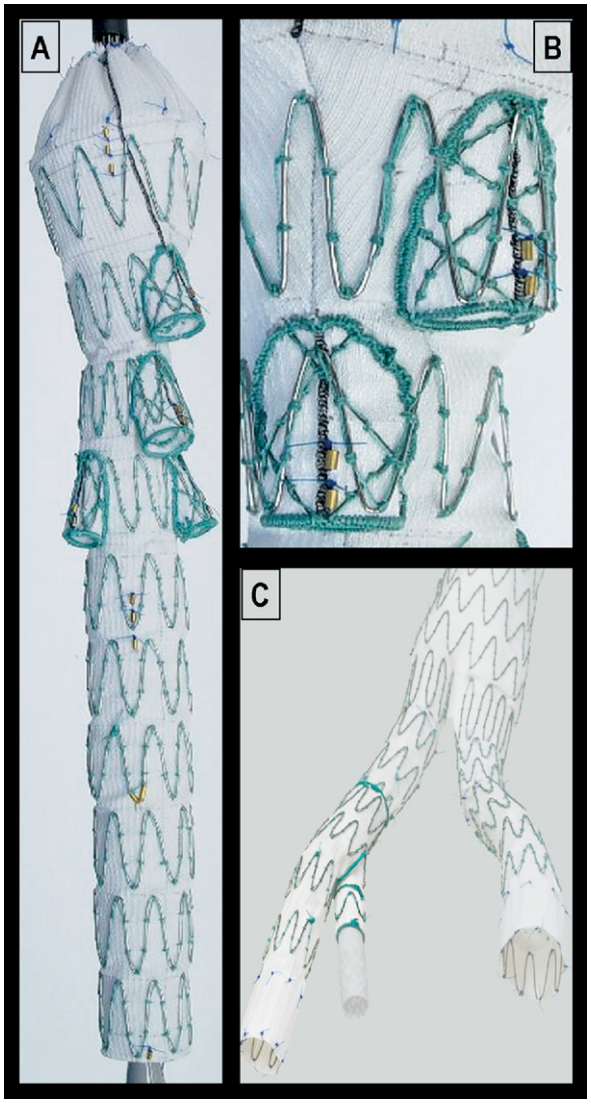

Fig 1. A, Branched stent graft with one free-flow stent, one internal sealing stent, followed by reducing stents, from which emerge the proximal side branch. **B,** Detail of the emergence of the side branches from the main stent graft module. **C,** Iliac side branch device.

thickness of regular open surgery grafts. The key difference is the presence of a reducing stent and side branches (Fig 1, *A* and *B*). The reducing stent, which is located distally to the sealing zone, converts the main body into a 16-mm, 18-mm. or 22-mm cuff-bearing segment. This diameter is planned based on the aortic lumen so that it can accommodate both the main body and the bridging covered stents between the graft side branches and the visceral vessels.

The diameter of the distal segment is adjusted to be sealed either to the diameter of a previous graft in those patients who have already undergone open or endovascular infrarenal aneurysm repair or return to a diameter of 22 mm, which will serve as a standard diameter for the overlap

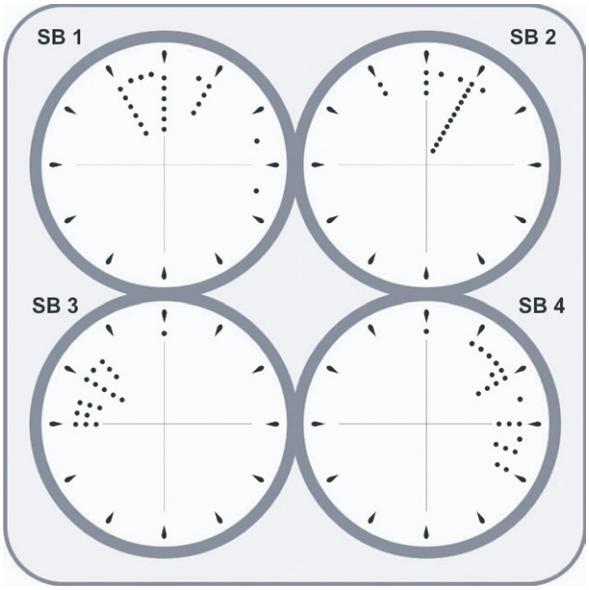

Fig 2. Distribution of the side branches *(SB)* in the first 21 stent grafts planned, relative to their clock position.

of a distal 24-mm bifurcated endograft that is placed simultaneously. Depending on the proximal extent of the aneurysm, additional Zenith TX-2 (Cook Medical Inc) endografts may be used proximally.

Two patients in this series had associated large bilateral aneurysms of the common iliac artery, so another branched device (Zenith Iliac Bifurcated Graft, Cook-Australia; Fig 1, *C*) was also used in one side, together with contralateral internal iliac artery coil embolization, according to the technique detailed elsewhere.[6]

The proximal sealing zone of the graft consists of one or two sealing stents with or without an uncovered proximal stent. Proximal barbs are added to the first sealing stent or to the uncovered stent. We have avoided these last stents when the landing zone is tortuous because we believe that their use tends to cause a type IA endoleak, as observed in our experience in the thoracic and abdominal aorta. Whenever possible, however, we prefer to use one sealing stent and one uncovered free-flow stent because we want to be able to cover the least extent of healthy aorta and yet create a graft landing zone that allows for good proximal fixation. This has a special relevance given the risk of spinal cord ischemia in these patients.

The side branches have 10, 18, or 21 mm in overlap length and are 6 or 8 mm in diameter (Fig 1, *A*). The planning of these branches follows two basic coordinates, namely, the distance from the graft edge and their respective clock position in the aorta at the point of emergence. Fig 2 depicts the distribution of the endograft side branches relative to their clock position in the 21 grafts planned so far, adapted to a four-branch graft, present in 75% of the patients in this small series.

This clock position distribution shows that although the planning is made individually, a clear pattern existed

between the side branches. Discrepancies may occur because these are the positions of the side branches and do not necessarily reflect the usual position of the typical visceral arteries found at the thoracoabdominal segment. For example, in patients with both the celiac trunk and the superior mesenteric artery (SMA) emerging at the same or approximate clock position, we tend to spread the side branches apart so that they are at least "1 hour" from one another; we found this to facilitate arterial catheterization during the procedure. Of the 21 grafts planned, 2 had 5 side branches (2 main left renal arteries, each), 16 had 4 side branches (celiac trunk, SMA, right and left renal arteries, except 1 graft with branches intended for the celiac truck and a hepatic artery and no right renal), 2 had 3 side branches (1 occluded celiac truck and 1 absent right renal artery), and 1 graft had 2 side branches (celiac trunk and SMA) and 2 reinforced fenestrations (right and left renal arteries).

The bridging between the graft side branches and each of the targeted visceral arteries is accomplished with Fluency covered stents (C. R. Bard Inc, Tempe, Ariz) with diameters preoperatively planned by CTA to match both the visceral vessel and the side branch diameter. Because this stent model is prone to kinking when flexed, we deploy a second bare, self-expanding nitinol Zilver Vascular stent (Cook Inc) inside the covered stent, with the same diameter or 1 mm larger for extra radial force at overlapping points and 1 cm longer to create a smoother transition from the covered stent into the visceral artery.

Surgical procedures. Patients are placed under general anesthesia for all interventions**,** which are performed in the surgical theater with C-arm subtraction (GE OEC Medical Systems, Salt Lake City, Utah). To lower the risk of spinal cord ischemia, a spinal catheter is placed in all patients, and cerebrospinal fluid (CSF) is drained to an external closed CSF drainage system set to maintain pressure <10 mm Hg during the first postoperative 48 hours, regardless of the presence or absence of neurologic symptoms. While in the intensive care unit (ICU), the patient's mean blood pressure is maintained at 90 mm Hg, urine output is monitored, and echocardiography is done frequently to assess left ventricular filling to optimize volume replacement. Continuous small doses of norepinephrine are used when needed to keep the pressure at goal level, as long as volume replacement is considered optimal.

If a branched iliac graft has to be placed, this is performed first in conjunction with contralateral internal iliac artery embolization (Fig 3). In future cases, as procedure times decrease, we maybe able to revascularize both internal iliac arteries with double iliac bifurcated devices; such procedures are already routinely performed in patients with bilateral iliac aneurysms, with or without infrarenal aortic aneurysms. To obtain access in patients with ≥8 mm iliac arteries, bilateral exposure of the common femoral artery through 4-cm transversal inguinal incisions is performed. Patients with an access vessel diameter of <8 mm undergo implantation of a retroperitoneal 10-mm Dacron iliac conduit.

Fig 3. A three-dimensional computed tomography angiography reconstruction shows a thoracoabdominal stent graft with four branches, in adjunct to left internal iliac artery revascularization with iliac side branch device and contralateral embolization of internal iliac artery.

The main branched graft is positioned with the side branches 1 to 2 cm above the target visceral vessels, as planned during the device-planning CTA study. Great precision at this point is not required because the bridging step can accommodate even a relatively large misdeployment error of about 60°; we have observed this in one patient, yet technical success to complete the procedure was achieved. Distal aortouniiliac or bifurcated grafts are then added to complete the system. Before the wires and delivery sheaths are removed from the iliac arteries, an angiogram is performed to confirm visceral perfusion through the side branches.

We then repair the femoral arteries with polypropylene sutures and proceed to the last step, which is the implantation of the bridging stents. This is accomplished through a left axillary artery exposure, as proximal as possible in the arm, to accommodate a 40-cm 12F sheath (Cook Medical) to maintain a workstation in the descending aorta, followed by a long 80-cm 10F Flexor sheath advanced distally into the visceral segment.

Predischarge CTA is performed using 1-mm slices if the serum creatinine concentration is within normal reference ranges; otherwise we plan CTAs for 1, 6, and 12 months, and yearly thereafter. Double antiagregant therapy with clopidogrel (75 mg daily) and aspirin (200 mg daily) is maintained for 3 months, and then aspirin (200 mg daily) is maintained for life.

RESULTS

Between August 2006 and April 2008, 23 patients (10 women, 13 men) with a mean age of 72 years (range, 68-79 years) were selected to undergo endovascular TAAA repair with branched, modular, custom-made devices. All patients were considered unfit for open procedures, mostly due to age, chronic obstructive pulmonary disease (COPD), coronary disease, or previous abdominal aortic surgery (isolated or not). All patients had hypertension.

Two patients were excluded after 1-mm-slice CTA analysis revealed extremely tortuous anatomy with no appropriate proximal landing zone for the graft. In 21 patients, the graft was planned according to their individual anatomy. During the wait for the devices to be produced, one patient died from aneurysm rupture and one patient underwent open surgery because of imminent aneurysm rupture. TAAA repairs were done in 11 patients, and the remaining eight are scheduled for surgery, depending on device production and availability. The mean follow-up period at present is 8 months (range, 18 days-21 months).

Technical success was accomplished in all 11 patients, without conversion, type I or III endoleaks, or limb occlusion. In conjunction with the repair of TAAA aneurysms, two bilateral common iliac aneurysms were treated with iliac branched devices at one side and embolization at the contralateral side (Fig 3). Two patients had a planned adjunctive iliac conduit implanted. One patient required unplanned successful emergency iliac artery reconstruction because of common iliac artery rupture during manipulation of a 24F sheath in a calcified 8-mm vessel. Temporary occlusion after the iliac artery rupture was obtained first with a CODA balloon (Cook Medical). Four patients did not need the distal graft because of appropriate anatomy (1 patient) or a previous AAA graft (3 patients).

Of the 43 target visceral arteries, two bridging stents for the celiac trunk could not be deployed due to unidentified chronic occlusion; these will be commented on later. Embolization of side branches was necessary in these two patients, without adverse outcomes. Two renal branches occluded: one intraoperative occlusion was followed by a fatal myocardial infarction (MI), and one other occlusion was noted at the 6-month follow-up, although this patient's serum creatinine and urine output remained within normal reference ranges.

Operative times varied widely, from 3 to 8 hours, depending on the need for iliac artery conduit implantation or on difficulties in catheterizing the celiac trunk, which required constantly longer times for bridging. The mean volume of low osmolarity contrast used was 193 mL (range, 48-420 mL). Eight patients required ≤4 days of intensive care unit (ICU) stay. One patient with CSF infection stayed at the ICU for 10 days. and another with a cerebellar stroke stayed for 20 days.

Three patients died, and two of these deaths were procedurally related. One patient sustained a massive myocardial infarction 1 hour after the procedure. The other patient had an ischemic cerebellar stroke on the first postoperative day and died 3 months later of pulmonary sepsis. The ischemic stroke might have been related to operative manipulation of the subclavian and, consequently, the vertebral artery. The third patient was readmitted because of abdominal pain 3 days after hospital discharge after an uneventful 5-day recovery, including 2 days at the ICU. He died 10 days later after emergency laparotomy that revealed non-necrotizing pancreatitis. The patient had a medical history of alcohol addiction, and during laparotomy, the patency of all four branches was confirmed by the general surgery team. The connection of this death to the procedure has not been clearly determined, but clinical evidence suggests no direct relationship.

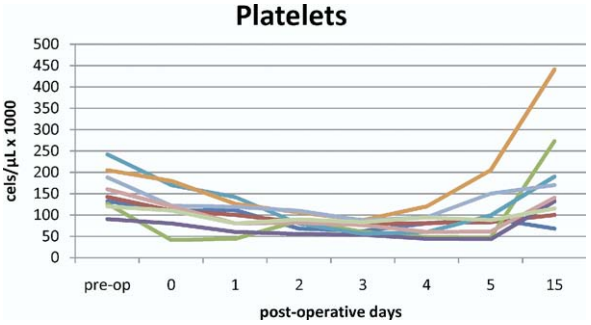

Fig 4. Platelet count at the night before surgery *(pre-op)*, on admission to the intensive care unit *(0)*, and on the following postoperative days in the 11 patients *(lines)* who underwent branched graft implantation.

To assess motor impairment to inferior limbs due to spinal cord ischemia, we adopted the Tarlov scale: 0, no movement; 1, slight movement; 2, sits with assistance; 3, sits alone; 4, weak hop; and 5, normal hop. One man had onset of a grade 3 lesion after the first 12 hours in the ICU, attributed to prolonged uncorrected hypotension. Spinal drainage was maintained >48 hours in an attempt to revert symptoms; but by day 4 a multisensitive gram-positive CSF infection had developed, which was successfully treated with regular antibiotics and removal of the catheter. Two women had a transitory grade 4 lesion for <24 hours, one on postoperative day 1 and the other on day 5, but hospital discharge was not delayed. One patient with previous COPD had a postoperative pneumonia that delayed hospital discharge, but intubation or readmission to the ICU was not required.

The striking hematologic and systemic inflammatory abnormalities observed by Chuter et al[7] in a similar series of patients were also observed in this series, with a notable drop in the platelet count, an increase in the white cell count, and an increase in C-reactive protein levels (Figs 4-7). The serum creatinine concentration otherwise remained stable in all patients but one; this patient's creatinine levels were elevated preoperatively, but he has not yet required dialysis after 17 months of follow-up. The

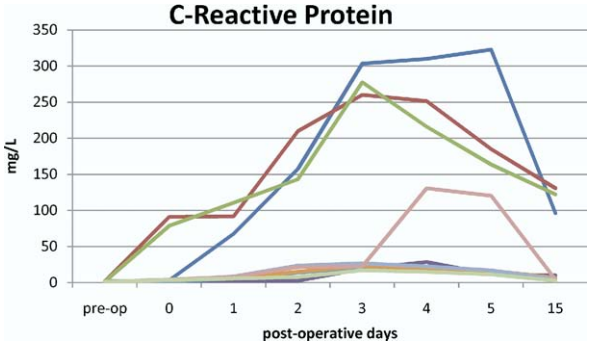

Fig 5. Levels of C-reactive protein on the night before surgery *(pre-op)*, on admission to the intensive care unit *(0)* and on the following postoperative days in the 11 patients *(lines)* who underwent branched graft implantation.

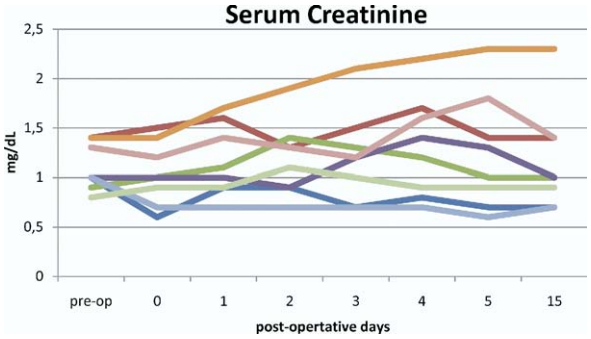

Fig 6. Levels of serum creatinine on the night before surgery *(pre-op)*, on admission to the intensive care unit *(0)* and on the following postoperative days in the 11 patients *(lines)* who underwent branched graft implantation.

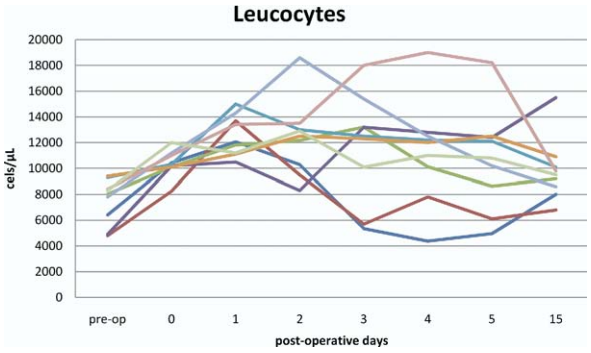

Fig 7. Leucocytes count on the previous night of surgery *(pre-op)*, on admission to the intensive care unit *(0)* and on the following postoperative days in the 11 patients *(lines)* who underwent branched graft implantation.

most common postoperative symptom was ileus, which responded well to fasting, nasogastric drainage, intense venous hydration, and regular prokinetic drugs within <5 days in three patients.

DISCUSSION

The report of this series does not pretend to nor is it capable of establishing that endovascular treatment with branched endografts is the standard therapy for a TAAA. We believe, however, after being involved with the process of planning the stent grafts as well as performing the interventions, that this is a useful option that already offers an effective alternative to patients who are at high risk for open procedures. One aspect not mentioned in most articles about TAAA is that once a patient is given the diagnosis of an aneurysm (especially one that cannot be treated with open surgery), a sudden change in lifestyle is usually observed, with a significant decline in the quality of life as patients become fearful of engaging in activities of daily life such as walking up the stairs or driving a car. Doctors often tell their patients that they have "a bomb in their belly," which causes anxiety and frustration in the patients and their families. We observed a significant improvement in the quality of life of patients and families after treatment.

Creating an appropriate access path for the graft is sometimes difficult, because we are frequently faced with highly calcified iliac arteries and because the delivering systems for these grafts are usually large (diameters of 22F and 24F). We adopted 8 mm as the lower limit for regular inguinal common femoral/iliac access. For smaller vessels or those with anticipated extreme calcification, we learned how to save time and be minimally invasive by placing an iliac conduit through a retroperitoneal iliac exposure. Usually this conduit can also be used as an adjunct bypass to stenosed iliac arteries, as has also been well described before.[7]

In one patient with previous infrarenal aortic endovascular repair, a disconnection of the contralateral iliac extension occurred during the passage of the branched endograft. This was only demonstrated later on CTA follow-up, and correction is currently scheduled after postponement due to a postoperative increase in the serum creatinine level >2.0 mg/dL (Fig 6).

The access required for the bridging step can also be challenging. One patient had a previous left internal mammary coronary artery bypass graft and we used transesophageal echocardiography to monitor cardiac signs of ischemia after placing a 12F sheath into the left subclavian artery. Placing it into the right side was considered to have a greater risk for cerebral embolization. Because the brachial artery is usually thinner than expected, we regularly perform the dissection of the third part of the axillary artery at the portion where the humeral arteries are seen, while special care is taken to protect the brachial plexus nerves from trauma.

The CTA in two patients showed highly stenosed but patent celiac trunks, and an intraoperative angiogram revealed short occlusion of the artery. A possible reason for this is because CTA does not reveal the flow direction as does contrast angiography. In both patients we faced a challenge to close the graft with the 8-mm side branches intended for the celiac trunk, and the solution was to

Table. Patient complications

Patient	*Sex*	*Age*	*ASA*	*Major comorbididity or surgery*	*Complications*		*Follow-up*	*Branch status*
					Perioperative	*Late (>30 days)*		
1	M	72	III	1. Ao surgery 2. MI	1. Pancreatitis 2. Death	NA	18 d	4/4
2	M	72	III	1. Stroke 2. GI cancer	1. Stroke	1. Pneumonia 2. Sepsis 3. Death	3 mon	3/3
3	M	68	III	1. MI	1. Renal occlusion 2. MI 3. Death	NA	NA	NA
4	F	75	III	1. HTS	None	None	21 mon	4/4
5	M	76	III	1. Ao surgery 2. COPD	1. Ileus 2. Paraplegia 3. Spinal catheter inf.	1. Urinary infection	18 mon	
6	M	74	III	1. Ao surgery	1. Ileus 2. RI–no dialysis	1. Previous Iliac limb disconection	17 mon	3/4[a]
7	M	79	III	1. MI	None	None	11 mon	4/4
8	M	68	III	1. COPD	None	None	7 mon	3/4[a]
9	M	74	III	1. COPD	1. Pneumonia (mild) 2. Ileus	1. Renal occlusion (no RI)	6 mon	3/4
10	F	72	III	1. Ao surgery	1. Transient paraparesis	None	2 mon	4/4
11	F	72	III	1. MI	1. Transient paraparesis	None	3 mon	4/4
Total		72		3 Ao–3 COPD–4 MI	3 Ileus; 2 paraparesis	5 None	8 mon	32/33

Ao, Aortic; *COPD,* chronic obstructive pulmonary disease; *GI,* gastrointestinal; *HTS,* hypertension; *MI,* myocardial infarction; *NA,* not applicable; *RI,* renal insufficiency.

[a]Side branches were deliberately embolized with coils during the procedure because the celiac trunk was not accessible.

deploy a covered stent from the branch into the aneurysm sac and fill it with coils. Control CTA in both cases showed no endoleak at 11 and 18 months, with no aneurysm increase in diameter.

The mortality and surgical indications for TAAAs have been classified into four types.[2,8] However, aortic coverage after open repair is generally different than after endovascular repair. Endovascular repair of a type IV aneurysm actually requires covering a proximal segment of healthy aorta above the diaphragm, thereby simulating in fact a type III repair; whereas a type I repair will require coverage of a normal aorta below the aneurysm, with extension similar to that of a type II repair. This might have future implications in predicting blood and fibrinolytic changes, systemic inflammatory responses, and spinal cord ischemia, although the real relationship between these has not yet been established, despite some initial reports.[9-11]

We suggest that in the future these patients should be classified according to the extent of the aortic coverage by the endograft instead of the extent of diseased aorta. This new classification will represent the real extent of endovascular operative trauma. In this series we were unable to correlate a decrease in platelet count, a rise in leukocyte count, and inflammatory markers to the length of the graft or to previous abnormalities in blood parameters as seen in other reports,[7,11] possibly because of the small number of patients included in this study. For the same reason we did not use a Kaplan-Meier survival curve to estimate survival; however, a detailed table with patient characteristics is provided (Table).

The current system used for endovascular repair of TAAA still has several deficiencies. Improvement in graft flexibility and applicability can be expected once a specific bridging stent is available to complete the system. Unfortunately, the currently available covered stents have a tendency to kink when flexed, lack conformability, and require large diameter sheaths placed into the axillary and subclavian arteries for delivery. The need for a second internal stent also increases costs, operative time, and the risks of complications. The availability of a standard device with prefabricated branches to treat at least 80% to 90% of TAAA aneurysms, as demonstrated in Fig 2, would eliminate the long waiting time for custom-made devices for most patients.

An increasing number of reports on branched stent graft technology indicate that this procedure might become a reality in the future for endovascular treatment of complex aneurysms in all aortic segments.[7,9,11-20] We share this opinion, having found that the use of available custom-made branched stent grafts is feasible and can be offered as a safe, effective alternative for patients with TAAAs, especially for high risk patients with clinical comorbidities that would preclude open surgical procedures.

AUTHOR CONTRIBUTIONS

Conception and design: MF, LL
Analysis and interpretation: MF, LL
Data collection: LL, MM
Writing the article: LL, MF
Critical revision of the article: MF, LL

Final approval of the article: MF, LL, MM
Statistical analysis: LL
Obtained funding: MF
Overall responsibility: MF

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DISCUSSION

Dr John Harris (Sydney, Australia). On several of the examples you showed us, the stent grafts were taken 3 to 4 cm into the visceral vessels. Why have you placed them so far into those arteries?

Dr Luiz Lanziotti. Well, two patients actually had visceral aneurysms, and we deployed the bridging stent way down into these arteries. We actually do not have an established pattern for that. It really depends on the procedure and how much overlap we feel is needed for each artery.